EXHIBIT 5

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

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In Re:

Bair Hugger Forced Air Warming

Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

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DEPOSITION OF ALBERT P. VAN DUREN

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MARCH 7, 2017

(The following is the deposition of ALBERT P. VAN DUREN, taken pursuant to Notice of Taking Deposition pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, via videotape, at the offices of Ciresi Conlin L.L.P., 225 South 6th Street, Suite 4600, Minneapolis, Minnesota, commencing at approximately 9:00 o'clock a.m., March 7, 2017.)

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P R O C E E D I N G S

(Witness sworn.)

ALBERT P. VAN DUREN

called as a witness, being first duly sworn, was examined and testified as follows:

ADVERSE EXAMINATION

BY MR. BANKSTON:

Q. Good morning, Mr. Van Duren.

A. Good morning.

Q. We're going to skip some of the formalities because I know you've been in that chair before, done some depositions, so we won't go over all of that today; I'm sure you're up to speed. But before we dive in, I did want to talk to you, make sure that you understood exactly what kind of deposition it is we're taking today, and -- and by that I mean that today you are appearing as a corporate representative for 3M. Do you feel like you have an understanding of what that is and what your purpose is here today?

A. I believe so.

Q. Okay. I'm going to be asking you questions, and in response to these questions today you're going to be giving testimony as though you're the voice of 3M. Obviously, I can't put 3M in that chair, so somebody has to be chosen. I've been informed that

difference between the 500 and the OR, is the changes you talked about making it suitable for operating room use?

A. That was -- that was one among many changes that were made in that series of warming units to distinguish them from warming units that were specifically designed for use in the PACU or the ICU.

Q. Okay. What is the purpose of having a filter on the Bair Hugger?

A. Well it had several purposes: one purpose is to prevent the fouling of the internal components of the Bair Hugger; the other is to reduce the particulates that enter and exit the Bair Hugger.

Q. As -- in the field of --

When designing the Bair Hugger, why did the company care about particulates coming in and out of the Bair Hugger?

A. To keep the electronics and the sensors, the fans and the heat exchangers from gathering debris and fouling.

Q. Okay. When -- when -- I'm --

What I'm specifically referring to is that when I asked you for the purpose, you gave me two purposes, one being to foul -- not to foul up the motor and the other to reduce particulates in and out

A. Okay.

Q. The filter plays a safety function; right?

MR. BLACKWELL: Object as asked and answered, but you can go ahead.

A. Well again, I think that the filter serves two purposes: one is to prevent the fouling of the internal components of the warming unit; and the other is to minimize the amount of particulates that are exhausted into the -- into the blanket.

Q. And that's a safety function; correct?

A. We -- we could view that as a safety function.

Q. Okay. When the 505 was being validated in its design, can you tell me what safety validation was done with respect to the filter?

A. I do not believe that any particulate filtration efficiency studies were completed at that time.

Q. Okay.

A. And I should just point out, I guess quickly, that the -- the filter media in the 505 was again designated as 0.2-micron level. The filters that were in the previous warming units, the previous model 200s and the 250s and the 275s, were somewhere around two microns, so 10 times less efficient or

for the 505's filter?

MR. BLACKWELL: I object to the form of the question.

A. Well again, the -- to --

To my knowledge, and based on my review of the records that I have available to me, I didn't see any testing related to particulate efficiency of the filter media.

Q. Okay. And so I take it by that same token there was no biological testing of the filter.

MR. BLACKWELL: I object to the form of the question.

A. I'm unaware --

The company is unaware of any biological testing conducted on the -- during the design of the 505.

Q. Okay. Let's talk a little bit, then, about the new media that comes into play, the M20 media that was introduced sometime in the 2000s period. Can you tell me: When that design change was made, what did the company do to ensure it was safe for the patients it would be used on?

A. Well the --

When the media was replaced, the design requirements specifications were again reviewed to

With respect to the safety validation for filter design, what requirements were -- there were and what was actually done on the model 750, that's not something you're prepared to talk about today.

MR. BLACKWELL: Object to the form of the question.

A. Well I mean I -- again, I can tell you that the -- there is a -- a control document, a design requirement specification, and it's controlled in the sense that it's like an ECO, that any requirement that's on that document is approved and signed off and it doesn't change without some sort of tracking occurring, that all of those specifications were met in -- in a -- or validated finally before the product was put on the market.

Q. Okay. But in terms of what was done pursuant to those specifications to validate the safety of this product with respect to airborne contamination, you don't know that.

A. I don't know that a specific requirement for airborne contamination exists on that document.

Q. Okay. Certainly, before the development of the model 750, the company was aware of the potential for airborne contamination and the necessity to take steps to mitigate that.

MR. BLACKWELL: I object to the form of the question.

A. We were aware that customers had concerns or perceptions about the level of particulates that might be ejected from a -- a forced-air warming system.

Q. Well in fact if we --

When we looked at Exhibit 47 today in front of you, in talking about the safety concerns that were addressed in the 510(k), one of those was airborne contamination; correct?

A. Yes.

Q. In other words, when the company was designing the 505 and making filter decisions, it understood that one risk that needed to be mitigated was the potential for airborne contamination.

A. Yes.

Q. So the same can be said true of the model 750. During that time of development, the company also understood that the product needed to take into consideration the potential for airborne contamination and take reasonable steps to mitigate that.

A. And it -- yes. And it did by including a filter --

Q. Okay.

A. -- as one component of that system.

Q. Okay. So as we saw, there was a certain kind of filter on the model 505, and we talked about how that was validated and all of those sorts of things, so I'm --

With respect to the model 750 and its filter, can you tell me specifically what was done to ensure that that product was safe in terms of airborne contamination?

MR. BLACKWELL: I object to the form of the question.

A. You know, I mean I think I've answered it the best I can. The -- the design requirements that dictate how the product is designed are tested to validate that the -- that those -- that the product meets those requirements specifications, so that was the -- in -- in total the amount of testing that was completed to validate the model 750. Specifically, I don't -- I do not think or do not recall that -- whether any safety testing, as you call it, was conducted.

Q. And that would be because, at this point anyway -- and I'm talking about the two thousand -- 1999-to-2002 timeframe -- the company did not have an appreciation of the importance of particulate matter that could be ejected into the operating room from the

Bair Hugger.

MR. BLACKWELL: I object to the form of the question.

A. Well I -- I --

The company certainly had an indication that it was important to the customers regarding the level of particulate loading that might occur from a forced-air warming unit.

Q. Okay. Now part of the reason that dictated a choice of filter in the model 750 was an airflow concern; correct?

A. Part of what, yes.

Q. In fact, it was a goal of the project of the 750 to create a device which delivered more air than the previous device.

A. Yes.

Q. Okay. So the air-output specifications of the unit changed and that in turn dictated some of the choice for the filter.

A. One -- one of the many design considerations that dictated that, yes.

Q. Okay. Before the 750 was ever released and sold and used on a patient, what was done to ensure that that change in air out -- output had no adverse effect on airborne contamination issues?

inconclusive as to whether or not the Bair Hugger unit 750 disrupts the sterile surgical field.

A. Well the 750 wasn't used in that study.

Q. Neither was the 505; correct?

A. No, I think it was the 505 in that study.

Q. 505E.

A. Well 505E, yes.

Q. Which has lower airflow than the 505.

A. Yes.

Q. Okay. And the 505E is not used in the United States.

A. No, it is not.

Q. Okay. With respect to surgical site -- disruption of the -- of the sterile field, you do not mention any CFD analysis. Did 3M do a CFD analysis, third party?

A. Yes.

Q. Okay. Would that fall under this category as well?

A. Well it's -- it's not a test, it's a -- it's a computational analysis.

Q. Okay. Well I take testing and analysis and calculations as all being tests in some way or other, whether a physical test or a calculation test. Is that fair? Is that the definition of testing?

Q. What are the flaws of the Huang study when you analyzed it?

A. I don't have my data here in front of me, but I'm sure that I've written extensively on that study.

Q. Do you agree the sample size was small?

A. Yes, I believe the sample size was pretty small in the Huang study.

Q. It was only 16 people; correct?

A. Yeah, I think so.

Q. It used the Bair Hugger 505; correct?

A. I believe that's the unit that was used.

Q. And that has less airflow than the 750; correct?

A. Yes.

Q. And Huang even acknowledges, and I think you acknowledged it in the Moretti study, that there's a higher count of particles or bacteria in the beginning of surgery in room air because of unrestricted movement of personnel in and out of an operating room.

A. Yes.

Q. So taking a sample size of CFUs or particles when you first lay down the patient is really not a good indicator of particles or CFUs with respect to what's really going on in an operating room during

coming from. Okay? Because particles are all over the operating room and underneath the operating room table and everywhere. Do you agree?

A. Yes.

Q. Okay. Based on the data that we have today, including the study funded by 3M as well as other studies, every single study indicates that the Bair Hugger increases the particle count over the sterile field; correct?

A. In absolute numbers, yes.

Q. Yes. Okay. And you have no internal studies to refute that; correct?

A. No, we don't.

Q. What's defendants' knowledge and analysis of third-party testing regarding whether or not the Bair Hugger causes surgical-site infection?

A. Well again, the analysis that I showed you that was done with the CDC data, for example. And the secular trend of deep joint infection over the last decade or so has generally declined in hip and knee implant surgery, so at a -- at a macro level there doesn't appear to be an increase in the number of these infections despite the fact that patients are generally older and sicker and there are more of them now than there were a decade ago.

analyzed or has knowledge of with respect to disruption of the sterile field. Is that a study that 3M has -- has knowledge and analyzed?

A. Yes.

Q. It is a study funded by Augustine Medical; correct?

A. Yes.

Q. And that study is flawed as well; isn't it?

MR. BLACKWELL: Object to the form of the question.

A. I mean I -- in --

In what way?

Q. Well is it flawed?

A. Perhaps it could be flawed.

Q. Well --

A. It may have limitations.

Q. You -- you -- you -- you -- you stated that all -- all studies are -- have some sort of flaws. Are you saying this study does not have any flaws?

A. All -- all -- all clinical trials have limitations in some way. There is no perfectly conducted trial, which is why we have to do many of them.

Q. Well Zink wasn't a clinical trial; was it?

A. It was a --

A. Limitations.

Q. Limitations, flaws.

Based on this analysis and knowledge, has 3M publicized these limitations of these studies of Zink and Kurz and Huang and Avidan to the public, to the consumers?

MR. BLACKWELL: Object to the question as beyond the scope of the 30(b)(6) designation.

A. No, we have not.

Q. Switching subjects, you would agree that the studies of third-party testing indicate that the Bair Hugger unit harbors bacteria inside the device.

A. Well I would -- I would agree that bacteria can be recovered from the interior of the device.

Q. Because the device is not sterile.

A. It's not sterile.

Q. And in fact, you're not -- 3M is not disputing that the Bair Hugger blower and hose can harbor bacteria inside the device.

A. We are not disputing that.

Q. Okay.

A. It's not sterile.

Q. Okay.

MR. ASSAAD: Take a five-minute break.

THE REPORTER: Off the record, please.

A. That's one of its purposes.

Q. All right. And you had some questions posed to you earlier today, or 3M did, that -- that shows -- pardon me -- with respect to knowledge about studies and increased particle counts. Do you recall that line of questioning?

A. Yes.

Q. And you testified on behalf of 3M that the company is aware that -- that studies show increased particle count when the Bair Hugger machine is turned to warm setting in operating rooms; correct?

MR. BLACKWELL: Object to the form of the question.

A. Trivial increases, yes.

Q. They --

But you are aware that the studies do show increased rate of particle count in operating rooms with the Bair Hugger set to warm; correct?

MR. BLACKWELL: Same objection.

A. Yes.

Q. And you'd agree that increased particle count is something that 3M has never warned orthopedic surgeons about; correct?

A. Not to my knowledge.

Q. So my question is -- is accurate?

asked him about changes that were made to the predicate device, which was the 200, which is what this is a picture of.

MR. BLACKWELL: So Exhibit 351 relates to the predicate device, the 200.

MS. ZIMMERMAN: Exactly. And the question ultimately is: Why was the warning removed when we got to the 500 series?

A. Well there's another difference, too, and that is that the 200 was not intended to be used in the operating room.

Q. Right. And -- and I'm aware of that, Mr. Van Duren. My question really is -- has to do with the knowledge that was available to the company broadly at that time.

There -- there was some knowledge, based on the fact that there is a warning of airborne contamination, that contamination could be airborne; correct?

A. Yes.

Q. Okay. And -- and despite that fact, there is no warning on the 500 series of the Bair Hugger device about risk of airborne contamination; correct?

A. That's correct.

Q. And that's despite the fact that the medical

care professionals rely on the company to warn about risks; correct?

MR. BLACKWELL: I object to the form of the question.

A. The risks that are known of, known about, yes.

Q. All right. And -- and -- and al --

That's also despite the fact that medical care professionals rely on the company to provide rules for safe use of a device; correct?

MR. BLACKWELL: I object to the form of the question.

A. Yes.

And it's very likely that the hazard analysis that occurred subsequent to the development of this device recognized that the risk index was either too low or zero and removed that warning from the labeling.

MS. ZIMMERMAN: I'm going to move to strike as non-responsive.

Q. Are you aware of any testing that -- that showed that there was not airborne risk of contamination --

A. I'm not.

Q. -- conducted by this study?

A. I'm not.

Q. Or I'm sorry, conducted by the company.

A. No, I am not.

Q. Okay. So it's pure speculation on your part.

Turning to the 700 series Bair Hugger, was -- was there any changes on the warnings as between the 700 series and the 500 series Bair Huggers?

A. I believe there were some changes.

Q. And what were those changes?

A. I believe the recommendation not to hose patients with the -- with the end of the nozzle was added.

Q. And hose --

And hosing is a practice of essentially using the machine without the disposable blanket attached; correct?

A. That's right.

Q. All right. Were there any other changes?

A. I'm -- I'm --

I suspect there are. I don't -- I don't know which ones changed between the two models though.

Q. So as you sit here today, the only change that you are aware of between the 500 and 700 series

with respect to the warnings has to do with the warning not to engage in hosing; correct?

A. That's correct.

Q. All right. And you'd agree that there's no warning on the 700 series, again, regarding the risk of airborne contamination; correct?

A. That's correct.

Q. And again, that's despite the fact that the risk of airborne contamination was in fact known to the company at that time; correct?

MR. BLACKWELL: I object to the form of the question.

A. It --

Well, it was included as a warning on the model 200, yes.

Q. Okay. I'm going to turn to topic number eight, which is data or research supporting the claim that the Bair Hugger blankets act as an additional filter or otherwise reduce the potential for contamination in the operating room. You're prepared to testify about that today as well; correct?

A. Yes.

Q. And I think you had some questions posed to you earlier today by my colleague, Mr. Assaad, regarding the Avidan study. Do you recall that?